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PROPOSAL TO STREAMLINE AND STRENGTHEN ENVIRONMENTAL REQUIREMENTS FOR BIOTECHNOLOGY FACILITIES

GENERAL OVERVIEW

March 2005

Introduction

From April 2003 to April 2004, the Massachusetts Biotech Council (MBC), MassDevelopment, and the Massachusetts Executive Offices of Environmental Affairs and Economic Development convened representatives of industry and government to make recommendations for how Massachusetts could retain and attract biotech manufacturing in the Commonwealth. In April 2004, the MBC issued draft recommendations including: a broad reaching education and technical assistance program; permit program enhancements at the state and local level; regulatory improvements; and innovative models to expedite siting new biotech facilities.

While the bulk of the recommendations were related to expediting facility siting, there were several recommended changes to operational requirements that are contained in regulations administered by DEP. DEP responded with a multi-program review to consider implementation of the MBC's recommendations and to identify additional changes that could be made in support of this effort. Generally, DEP's two-pronged goal was to strengthen and clarify environmental standards for the biotech industry while streamlining regulatory process or permitting requirements. As a result, DEP is proposing to implement most of the MBC recommendations pertaining to State environmental requirements through changes to its regulations. DEP also identified and is proposing other changes, in addition to those recommended by the MBC, which will clarify and strengthen environmental standards and create certainty and savings for business.

DEP is proposing amendments to the air quality and industrial wastewater regulations that will be available only to biotechnology companies that manufacture products regulated by the U.S. Food and Drug Administration (FDA) as drugs, biologics, or medical devices. Also in these

regulations, the Department is proposing a regulatory definition of biotechnology. In addition, DEP is proposing to amend the hazardous waste regulations. These amendments, however, will be widely available to other industries beyond biotech.

This document provides a general overview of DEP's biotech project. There is list of attachments at the end of this discussion. More detailed, individual background documents on each of the proposed regulation changes are included in these attachments.

Air Quality

DEP is proposing amendments to the air regulations (310 CMR 7.00) that include two exemptions from plan approval (i.e. permit) requirements for biotechnology operations that have the potential to emit volatile organic compounds (VOC).

There is an unconditional exemption from the plan approval requirement proposed for biotechnology laboratories. Generally, laboratories use and emit very small amounts of volatiles in dispersed cleaning applications that are very difficult to collect and control. It is unlikely that VOC emissions from a laboratory will reach the existing permitting threshold of one ton of emissions per year; nonetheless, the exemption from plan approval is proposed in order to provide certainty about the air pollution requirements for labs. This exemption is available to laboratories that are involved in research, development or support for biotechnology products that are either undergoing preclinical research in preparation for, or are the subject of, FDA regulatory applications or notices.

A conditional exemption from plan approval, commonly known as a permit-by-rule, is proposed for surface disinfection processes used to manufacture biotech products. Surface disinfection would be exempt from plan approval provided that total facility-wide emissions are below specific yearly and monthly caps for VOCs and Hazardous Air Pollutants (HAPs). Chemical usage records would need to be kept to verify emission levels. The proposed exemption is further conditioned with performance standards that are at least as protective as the conditions that would otherwise be applied in individual permits for these operations. The emissions caps set in the proposed regulations would create an incentive to keep emissions of VOCs low. This conditional exemption is available only to biotech operations that are manufacturing products for which Investigational Notices or Applications have been filed with the FDA.

Prior to the MBC recommendations and the commencement of this biotech streamlining project, DEP had proposed regulations with a similar conditional exemption from plan approval, or permit-by-rule, for engines and turbines. This exemption will be available to all Massachusetts industries, including biotech. The type of equipment covered is frequently installed for back-up electric power generation by many kinds of industry, biotech included. The regulations set design and performance standards for engines and turbines that result in limitations on the pollutants created by combustion. The proposed regulations, not included here, have been through public hearing and will be promulgated soon.

It should be noted that the biotech industry, like all other industry that emits an air waste stream, must keep track of all air pollutant emissions; even emissions from the processes that fall under

these exemptions must be counted when calculating total facility-wide emissions, for any purpose.

These three exemptions provide relief from permitting requirements while setting clear standards that are at least as protective of air quality as individual permits would be.

Hazardous Waste Management

The Massachusetts hazardous waste statute (M.G.L. Ch. 21C) allows DEP to waive requirements of Ch. 21C when DEP determines that a particular hazardous waste or activity is "insignificant as a potential hazard".

The Department is proposing to amend the hazardous waste regulations (310 CMR 30.0000) by: 1) to allowing hazardous waste generators to apply on a case-by-case basis for a waiver of the requirements of the regulations; and 2) establishing a blanket waiver of the requirement for a treatment license for elementary neutralization of aqueous corrosive wastes at the site of generation. These provisions would be available to any generator of hazardous waste, not just the biotech industry.

The proposed amendments will allow hazardous waste generators to apply to the Department on a case-by-case basis for waivers from requirements of 310 CMR 30.0000 and sets forth the information they need to provide the Department. They the process and criteria the Department will use in reviewing those applications.

The blanket waiver proposed here is to allow the treatment of aqueous corrosive wastes in Elementary Neutralization Units (ENUs) without a license. The proposed regulation defines management and testing standards and requires notification to the Department. The treatment process is simple and straightforward, and lends itself to general standards as are proposed here.

In addition to these proposed amendments to the Department's regulations, the Department and U.S.EPA Region 1 have agreed on a joint guidance document that resolves their differing interpretations of standards for satellite hazardous waste accumulation in laboratories. This memorandum, dated September 28, 2004, and entitled "Clarification on the Applicability of the Satellite Accumulation Rule to Laboratories," describes practices that companies should adopt to assure compliance and safe management of small amounts of hazardous waste generated in laboratories. It clarifies how the satellite accumulation rule is to be applied to laboratories, provides the generator with regulatory certainty, and ensures consistency between state and federal agencies in enforcement of this rule in Massachusetts. This guidance is available at *(on DEP's website - URL to be added)*.

Industrial Waste Water

DEP is proposing to add a section to the Water Pollution Control regulations (314 CMR 17.00) containing a comprehensive industrial wastewater standard for biotech operations discharging to sewers, other than those under the authority of the Massachusetts Water Resources Authority (MWRA). (DEP has delegated authority to the MWRA to administer state sewer discharge

permits in its service area.) The new regulation would be available to biotech companies that discharge to sewers under the authority of Publicly Owned Treatment Works (POTWs) with U.S. EPA approved Industrial Pretreatment Programs (IPPs). Currently, 47 of the 130 POTWs in the Commonwealth have approved IPPs. Discharges to sewers regulated by sewer authorities without IPPs would not be eligible for this standard and would be subject to existing state permitting requirements for industrial wastewater discharges to sewers. Discharges to ground or surface waters will also continue to be subject to state permits.

The proposed regulation would provide conditional exemptions from the requirements for a state sewer discharge permit, industrial wastewater treatment system plan approval, and certified operator staffing plan approval by the Department. It includes numerical effluent limits, management standards, monitoring, and reporting requirements for discharges. It classifies (or grades) seven industrial wastewater treatment system types with respect to their complexity and defines streamlined certified operator staffing requirements. The regulation also requires a report of the toxics in use at the facility that have the potential to be discharged to the sewer (mirroring an MWRA requirement) and a compliance certification to the Department.

Similar to the air quality conditional exemption, these conditional exemptions from industrial waste water permits and approvals would be available only to biotech operations that manufacture products regulated by the FDA as medical devices, drugs, or biologics, and for which appropriate Investigational Notices or Applications have been filed with FDA.

Biotech operations would continue to be subject to local sewer permits and limits. The numerical limits and management standards in the proposed regulation are intended to provide a basic level of protection across the Commonwealth and to complement limits set by local sewer authorities. Where local authorities set effluent limits for chemicals that are also limited by this regulation, the stricter of the two would apply.

Right to Know

The Department reviewed the Right to Know (RTK) law and regulations (M.G.L. c.111F, Section 16 and 310 CMR 33.00) to determine if the requirement that all Material Safety Data Sheets (MSDS) for chemicals used in industry be filed with DEP annually could be changed so that MSDSs would be filed only upon DEP's request. DEP has determined that the statute requires that the MSDSs be filed with DEP. The statute would have to be amended to change this requirement.

Fees

The Department is not proposing fees in this regulatory package. It may, however, amend its fee regulations (310 CMR 4.00) to address the Department's costs for these programs.

Questions for Reviewers

1. These regulations propose a regulatory definition of biotechnology on which the Department would like comment.

2. The proposed exemptions from air quality and industrial wastewater plan approvals and permits would be available to biotechnology companies that are making products regulated by FDA as drugs, biologics, or medical devices. The Department would like to know how many biotechnology companies in Massachusetts make products that do not fall into one of these three classes.

3. These exemptions are also only available to biotech companies that have filed Investigational Notices and Applications for clinical trials (Investigational New Drug Application, Investigation Device Exemption Notice, New Drug Application, a premarket approval application, or a premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) (including an FDA-approved exemption from the 510(k) premarket notification requirement). The intent is to make these exemptions available to companies just as they reach manufacturing scale so that capital expenditures are made with long-term compliance in mind. What are the pros and cons of making this FDA filing the point at which the regulations take effect?

4. Is it the case that some biotech products developed in the U.S. undergo clinical trials in countries other than the U.S. and, as a result, FDA filings may not be required? If the country hosting the trials has its own regulatory process or no regulatory process similar in purpose to that of the FDA, when should the operations manufacturing products for these trials be subject to the proposed regulations?

Attachments

1. Proposed amendments to 310 CMR 7.00, Air Pollution Control
    - Background Document
    - Definition: Biotechnology
    - 7.02(2) Exemptions from Plan Approval: 7.02(2)(b)(33) Biotechnology Laboratories,
    - 7.03(3) Plan Approval Exemption: Construction Requirements: 7.03(3)(25) Biotechnology Surface Disinfection Processes.

2. Proposed amendments to 310 CMR 30.000, Hazardous Waste Management
    - Background Document
    - 30.101 Definitions: Elementary Neutralization, Elementary Neutralization Unit
    - 30.3430(8) and 30.351(11) cross reference to waiver for corrosive wastes treated in an ENU
    - 30.501(2)(h) and 30.601(2)(h) clarification regarding management standards for generators that are treating with ENUs
    - 30.801(17) – adds ENU as a form of treatment which does not require license to treat a hazardous waste
    - 30.1100 – Wastes and Activities Subject to Waiver

- 30.1101 – General Requirements for Wastes and Activities Subject to Waiver
- 30.1102 - Case-by-Case Waiver Determinations for Specific Hazardous Wastes and Activities
- 30.1103 – Treatment of Corrosive Hazardous Waste in an Elementary Neutralization Unit.

3. Proposed 314 CMR 17.00, Water Pollution Control and Amendments to 257 CMR 2.00, Certification of Operators of Wastewater Treatment Facilities.

- Background Document
- 17.01 Purpose
- 17.02 Definitions
- 17.03 Applicability
- 17.04 Exemptions
- 17.05 General Requirements
- 17.06 Effluent Limits and Requirements
- 17.07 Monitoring Requirements
- 17.08 Industrial Wastewater Treatment System Grading
- 17.09 Staffing Requirements for Industrial Wastewater Treatment Systems
- 17.10 Operation and Maintenance Requirements for Industrial Wastewater Treatment Systems
- 17.11 Recordkeeping for Industrial Wastewater Treatment Systems
- 17.12 Reporting
- 17.13 Enforcement

- 257 CMR 2.04(2) Exemption for facilities operated in compliance with 314 CMR 17